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510(k) Summary
for
NeuroMetrix SENSUS Electrode

SPONSOR

NeuroMetrix, Inc.
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NOV 26 2012

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: November 7, 2012

DEVICE NAME

Proprietary Name: SENSUS Electrode
Common/Usual Name: Transcutaneous Electrical Nerve Stimulator Electrode
Classification Name: 882.1320 GXY
Cutaneous Electrode

PREDICATE DEVICE

Lead-Lok Reusable Neurostimulation Electrodes (K010431)

INTENDED USE

The NeuroMetrix SENSUS Electrode is intended for use as disposable, conductive, adhesive interface between the patient's skin and a transcutaneous electrical nerve stimulator.

DEVICE DESCRIPTION

The SENSUS Electrode provides an electrically conductive interface between a transcutaneous electrical nerve stimulator and a patient's skin. It is provided non-sterile, is designed and intended for single patient use only, and to be disposable.

The SENSUS Electrode is comprised of four individual electrodes, each of size 36 by 46 mm. The overall dimensions are 50 by 280 mm. The individual electrodes are electrically connected in pairs such that the two outer electrodes constitute one pair and the two inner electrodes constitute a second pair. The SENSUS Electrode contains two conventional male snap connectors for electrical connection to a transcutaneous electrical nerve stimulator.

The SENSUS Electrode has a multi-layer design. The first and outermost layer is a sheet of Mylar. The second layer contains conductive silver traces and silver electrode pads. Where the silver traces are not covered by hydrogel, they are covered by a dielectric mask. The third layer is the four individual electrodes which consist of a medical grade, self adhering, biocompatible hydrogel (KM-10G, Katecho, Inc., Des Moines, IA). When not in use, the hydrogel is covered by a Mylar release liner. Two male type snap connectors interface the SENSUS Electrode to the transcutaneous electrical nerve stimulator. The patient facing surface of the snap connectors are either under hydrogel or covered by a laminated dielectric polypropylene layer. Therefore in both cases the snap connectors do not directly contact the patient's skin.

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COMPARISON TO PREDICATE

The SENSUS Electrode and Lead-Lok Neurostimulation Electrodes have the same intended use. Both are intended as single-patient/multiple application use, conductive, adhesive interfaces between electrical stimulators, such as transcutaneous electrical nerve stimulators, and a patient's skin. Both are prescription devices to be used under the direction of a medical professional.

The table below compares the intended use and characteristics of the SENSUS Electrode and the predicate Lead-Lok Reusable Neurostimulation Electrodes. The two devices have the same intended use, utilize similar materials, and have similar technological characteristics. The primary difference between the two devices is that the SENSUS Electrode consists of four individual electrodes arranged in a pre-set geometry whereas the predicate electrodes are not pre-combined into a specific geometry. The combination of individual electrodes into a pre-configured array is a convenience feature that does not alter the basic function of the individual electrodes, which is to conduct electrical currents from a stimulator to the patient's skin. Furthermore, the SENSUS Electrode shape and area fall within the range of the predicate. As a result, the technological characteristics of the SENSUS Electrode do not raise new questions of safety or effectiveness.

This comparison of the SENSUS Electrode and predicate Lead-Lok Neurostimulation Electrodes, along with testing data provided in this submission, support a finding of substantial equivalence for the SENSUS Electrode.

	NeuroMetrix SENSUS Electrode	**Lead-Lok Reusable Neurostimulation Electrodes (K010431)**
General Characteristics		
Intended Use	The NeuroMetrix SENSUS Electrode is intended for use as a disposable, conductive, adhesive interface between the patient's skin and a transcutaneous electrical nerve stimulator.	Lead-Lok Reusable Neurostimulation Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator
Number of Electrodes	4, two pairs of two electrodes	1
Sterility Status	Non-sterile	Non-sterile
Single-Patient Use	Yes	Yes
Multiple Applications	Yes	Yes
Reusable (across patients)	No	No
Shelf-life	24 months, shelf-life to be confirmed with accelerated aging test prior to commercial distribution	Unknown
Technical Characteristics		
Substrate (1st layer)	Polyethylene	Polyethylene, polypropylene
Electrical Conductor (2nd layer)	Ag	Carbon coated with Ag/AgCl
Hydrogel (3rd layer)	Katecho KM10G	Katecho KM10 series gels
Connector	Male snap connector	Male snap connector
Overall Dimensions	5 x 28 cm, total area 140 cm^2, includes two electrodes	Various shapes (square, circle, oval, butterfly) with total area 7.9 – 154.8 cm^2
Conductive Surface (single electrode) Dimensions	Two rectangular 3.6 x 4.6 cm connected pads, total area 33.1 cm^2	Various shapes (rectangular, circle, oval) with total area 7.9 – 154.8 cm^2

GUIDANCE DOCUMENT

The recommendations of the FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Cutaneous Electrode (April 5, 2010)" were taken into account in preparing this 510(k) submission. The draft guidance addresses requirements for cutaneous electrodes which are

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defined as "*an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.*" This definition includes electrodes intended for use with transcutaneous electrical nerve stimulators. NeuroMetrix believes that SENSUS Electrode complies with the special controls as outlined in the draft guidance, thereby providing additional assurance of safe and effective use of the SENSUS Electrode.

NON-CLINICAL TESTING

Verification testing of the SENSUS Electrode includes electrical and mechanical tests to show that it meets its target specifications over a range of operating and storage conditions. Verification and performance testing further demonstrate that it meets user needs as reflected in the functional specification.

Biocompatibility Testing

The hydrogel pads, forming the individual electrodes, maintain contact between the SENSUS Electrode and the skin. This contact is established by the hydrogel's self-adhesives properties. The SENSUS Electrode hydrogel is KM-10G manufactured by Katecho, Inc. The KM-10G is a member of the Katecho KM-10 series that has been used in electrodes previously cleared for use with transcutaneous electrical nerve stimulators (K000870). Katecho has established biocompatibility of the KM-10G hydrogel through testing of two related hydrogel formulations. The KM-10G hydrogel has essentially the same formulation as the Katecho KM-10B hydrogel with the exception of a higher concentration of diacetone acrylamide (DAA). Another Katecho hydrogel, KM-10P, has a similar concentration of DAA. Therefore the biocompatibility of the KM-10G hydrogel was established by combining the test results for the KM-10B and KM-10P hydrogels.

Electrical and Mechanical Testing

Electrical performance was assessed by measuring the AC impedance of electrodes in a gel to gel configuration and evaluating current dispersion across the surface of the electrodes. Adhesive performance was evaluated by performing a skin adhesion test. Electrode stability was evaluated by assessing electrical performance under normal use conditions. Cutaneous electrode materials should be stable and resist physical and chemical breakdown as a result of conducting electrical current. To assess this, SENSUS Electrodes were tested to ensure they met the electrical impedance specifications after 1 hour of conventional use. Accelerated aging shelf-life testing was performed to ensure that the SENSUS Electrode performs as intended over the course of its labeled shelf-life. The electrical and mechanical properties of the snap connectors were assessed by measuring the resistance of the connection and the connection retention force.

The SENSUS Electrode conforms to the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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CLINICAL TESTING

NeuroMetrix determined that non-clinical (i.e., bench) testing was sufficient to demonstrate that the SENSUS Electrode is as safe and effective as the predicate.

CONCLUSION

The verification and performance data presented in this 510(k) submission demonstrate that the SENSUS Electrode is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 26, 2012

NeuroMetrix, Inc
c/o Mr. Rainer Maas
Director of QA/RA
62 Fourth Avenue
Waltham, MA 02451

Re: K121816
Trade/Device Name: SENSUS Electrode
Regulation Number: 21 CFR 886.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 7, 2012
Received: November 8, 2012

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

Malvina B. Eydelman, M.D.
Director
Division of Opthalmic, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K121816

Device Name: NeuroMetrix SENSUS Electrode

Indications for Use:

The NeuroMetrix SENSUS Electrode is intended for use as disposable, conductive, adhesive interface between the patient's skin and a transcutaneous electrical nerve stimulator.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K121816